3. SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

SPONSOR:

BioMimetic Pharmaceuticals, Inc.
389A Nichol Mill Lane
Franklin, TN 37067

Contact: Sandra Williamson
Manager, Regulatory Affairs

DEVICE TRADENAME:

OsteoMimetic™ Synthetic Bone Matrix (*OsteoMimetic* matrix)

COMMON OR USUAL NAME:

Resorbable calcium salt bone void filler device

CLASSIFICATION:

Class II; 21 CFR 888.3045 (ProCode MQV)

PREDICATE DEVICE:

Depuy Conduit™ TCP Granules, K014053
Synthes chronOS, K013072
OrthoVita VitOss™ Scaffold Synthetic Cancellous Bone Void Filler, K994337

DEVICE DESCRIPTION:

OsteoMimetic Synthetic Bone Matrix is a synthetic, multicrystalline, porous form of β-tricalcium phosphate [$Ca_3(PO_4)_2$]. The matrix physically fills bone defects to prevent the collapse of soft tissue and stabilize the blood clot. It provides a biocompatible, osteoconductive, and three-dimensional scaffold to facilitate new bone formation. As the matrix is resorbed, bone and other connective tissues grow into the space previously occupied by the matrix. *OsteoMimetic* Synthetic Bone Matrix is provided sterile as 1-2mm particles.

SAFETY:

OsteoMimetic matrix is tested to conform to ASTM F1088 "Standard Specification for Composition of Beta-Tricalcium Phosphate for Surgical Implantation." Biocompatibility was established based on ISO 10993 biocompatibility testing. The predicate devices to which substantial equivalence is claimed have been used safely for many years in the clinical environment.

INTENDED USE:

OsteoMimetic matrix is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. The *OsteoMimetic* matrix is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone in conjunction with standard measures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2005

Ms. Sandra Williamson
Manager, Regulatory Affairs
BioMimetic Pharmaceuticals, Inc.
389-A Nichol Mill Lane
Franklin, Tennessee 37067

Re: K051775
Trade/Device Name: OsteoMimetic™ Synthetic Bone Matrix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: July 1, 2005
Received: July 1, 2005

Dear Ms. Williamson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051775

Device Name: *OsteoMimetic*™ Synthetic Bone Matrix

Indications for Use:

OsteoMimetic™ Synthetic Bone Matrix is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. The *OsteoMimetic* matrix is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone in conjunction with standard measures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510K # K051775

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051775